It is submitted that this is not a viable position.

The invention relates to an oral or dermal medicinal composition containing a pharmaceutical active substance and a thermoplastic coating and binding agent prepared by a method of applying a thermoplastic coating and binding agent in a hot-melt liquid state to said oral or dermal medicinal composition, followed by cooling to solidify the thermoplastic coating and binding agent, wherein said thermoplastic coating and binding agent consists essentially of a non-homogenous mixture of, based on 100% by weight of A and B:

A) 5-95% of a thermoplastic acrylic plastic with a melting temperature above room temperature and below 200°C, a glass transition temperature below 120°C, and a melt viscosity pf 1,000 to 1,000,000 Pa-sec at the melting temperature; and

B) 95-5% of a flow improver, which, at room temperature, is not compatible with the thermoplastic acrylic plastic, has a melting temperature above room temperature but below 200°C, a weight average molecular weight under 20,000 d, and a melt viscosity below 100 Pa·sec at the melting temperature of the acrylic plastic.

An essential and critical feature of the invention of the Canadian patent is the presence of at least 5 wt% of a water-soluble hydroxy alkyl cellulose or hydroxy alkyl methyl cellulose.

Note its disclosure at pages 2 and 3:

> ...a solid depot drug form product by melt extrusion at from 50 to 200°C and continuous shaping of a mixture of from 0.1 to 70% by weight, based on the finished depot form, of a pharmaceutical active ingredient with a polymer melt of the following composition:
>
> a) at least 6% by weight, based on the complete depot form, of at least one water-insoluble poly(meth)acrylate with a glass transition temperature Tg in the range of from -60 to 180°C,
>
> b) a water-soluble hydroxyalkylcellulose or hydroxy-alkylmethylcellulose with 2 or 3 carbons in the hydroxyalkyl,

or an N-vinylpyrrolidone polymer with from 0 to 50% by weight of vinyl acetate or a mixture of the two in the ratio a):b) = 5:95 to 95:5, and

c) 0-30% by weight, based on the finished depot form, of one or more conventional pharmaceutical auxiliaries,

In other words, it discloses a composition of a homogenous mixture of a) and b), optionally also containing component c). Such a composition clearly is distinctly different from the composition used in the preparation of the claimed medicinal composition consisting essentially of a non-homogenous mixture of A and B as defined by the claims, i.e. not containing essential component b) of the Canadian Patent. The "consisting essentially of" limitation of the claims clearly precludes the presence of the hydroxyalkylcellulose or hydroxyalkylmethyl cellulose essential and critical in the composition of the Canadian patent. How then can it reasonably be said that the omission of such an essential component is obvious? Manifestly, the artisan would not so interpret the teaching of the reference. On this basis alone, the claims patentably distinguish over the Canadian patent.

Further, polyethylene glycols optionally being present in the Canadian patent are neither further characterized nor illustrated by specific examples thereof, particularly with regard to molecular weight. In the claimed invention, on the other hand, such molecular weight is significant and so claimed. Note also, page 12, line 20 to page 13, line 17 of the specification discussing its significance.

Additionally, hydroxyalkylcellulose usually have molecular weights much greater than 20,000 d. The claims thus clearly also are not readable on the Canadian patent also for this reason.

Similarly, in the European patent two lipid excipients, one of which can dissolve or gel component A while the other acts as a lubricant, or, alternatively, a single lipid excipient having both of these functions is used in the extrusion of a medicinal material. Here again, the reference teaches away from the claimed invention in requiring that the composition be a homogenous mixture, i.e., containing a lipid excipient which can dissolve the gel component A. Such is contrary to the express requirement of the present claims wherein the mixture of A and B is specifically defined as consisting essentially of a non-homogenous mixture of A and B.

In particular, with regard to the European patent, it is pointed out to the Examiner, as so disclosed at page 6, lines 1 to 5 of the translation thereof, that a homogeneous granulate consisting of a mixture of one or more polymers and of one or more lipid excipients containing the active substance is an essential and inventive aspect of this reference. Note also, page 4, lines 16 to 18 of the translation that the lipid excipient must have a solubilizing effect on the polymer. Certainly, a non-homogeneous mixture as claimed is not inherent in the prior art composition. Note that when a non-homogeneous mixture would be obtained by using an excipient of the classes of materials disclosed by the European patent, such excipient would not be useful for attaining Patentee's objective. Homogeneity depends not only on the requisite selection of a particular excipient, but also in combining such selected excipient with a particular polymer. Thus, while in Example 17 of the European patent referred to by the Examiner, a polymer within the scope of the claims is present, nevertheless, only a

specific excipient is illustrated as being combinable therewith. In the claimed invention, on the other hand, contrariwise, the selected combination must be such so as to obtain a non-homogeneous mixture.

It is again additionally pointed out that the claims specifically call for applying a non-homogenous mixture of the thermoplastic coating and binding agent in a hot-melt liquid state to an oral or dermal medicinal composition. As so disclosed at page 7, lines 5 to 8 of the specification:

> The incompatibility has the effect that in the solidified melt, components A and B are present as separate phases, and flow improver B is not present dissolved in polymer phase as a plasticizer.

It is thus essential that the initial mixture be non-homogenous, such non-homogeneity resulting in the above set forth effect. Using a homogenous mixture, as in the reference, palpably would not result in such an advantageous effect.

The defined incompatibility, i.e., non-homogenous mixture, has the effect that in the solidified melt, components A and B are present as separate phases, and flow improver B is not present dissolved in polymer phase A as a plasticizer. Such provides for an improved flowing capacity of the melt, without a plasticizing effect which would lead to sticky surfaces. Such clearly is not obvious from the references.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §103 over the cited references is requested.

It is submitted that the claims define a patentable invention. Their allowance, as well as of the method claims of the same scope to be rejoined with the product claims, thus is solicited.

Respectfully submitted,

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